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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/977,064	10/11/2001	David J. O'Reilly	5050-0031	1787
27194	7590	05/23/2005	EXAMINER	
HOWREY SIMON ARNOLD & WHITE, LLP c/o IP DOCKETING DEPARTMENT 2941 FAIRVIEW PARK DRIVE, SUITE 200 FALLS CHURCH, VA 22042-2924			ZEMAN, MARY K	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 05/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/977,064

Applicant(s)

O'REILLY ET AL.

Examiner

Mary K. Zeman

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 17-22 is/are pending in the application.
- 4a) Of the above claim(s) 17-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-12 and 17-22 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 12/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/4/05 has been entered.

Claims 1-12 are pending in this application. Claims 17-22 stand withdrawn from consideration as being drawn to a non-elected invention.

Applicant's arguments filed 3/4/05 have been fully considered but they are not completely persuasive.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Amended claims 1 and 7 contain the phrase "wherein the product enables the user to test a hypothesis based on the correlation of the first and second database records. (or drug signatures)" While these words appear in the specification, the specification as originally filed is not enabling for this limitation. The specification fails to set forth how a product enables one to test a hypothesis, or how that testing would be accomplished. It is unclear what hypotheses are being referred to, or how it is to be formed based on the two records obtained by the claimed methods. While the skill in the art of bioinformatics is high, it would require undue experimentation for one of skill in the art to determine what hypotheses can be formed, and then how to use the product to test the

Art Unit: 1631

hypothesis. These decisions require inventive decision making beyond that which is disclosed in the specification. Removal of this phrase would obviate this rejection.

Claims 10 and 12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 10 and 12 have been amended to recite various “means for” clauses. The means for the differing selecting steps, and the means for identifying lack specific related structures in the specification. No specific computer, software or system structures for performing these means are disclosed. See MPEP 2181: 35 U.S.C. 112, sixth paragraph states that a claim limitation expressed in means-plus-function language “shall be construed to cover the corresponding structure...described in the specification and equivalents thereof.” “If one employs means plus function language in a claim, one must set forth in the specification an adequate disclosure showing what is meant by that language. If an applicant fails to set forth an adequate disclosure, the applicant has in effect failed to particularly point out and distinctly claim the invention as required by the second paragraph of section 112.” *In re Donaldson Co.*, 16 F.3d 1189, 1195, 29 USPQ2d 1845, 1850 (Fed. Cir. 1994) (in banc)... Whether a claim reciting an element in means- (or step-) plus-function language fails to comply with 35 U.S.C. 112, second paragraph, because the specification does not disclose adequate structure (or material or acts) for performing the recited function is closely related to the question of whether the specification meets the description requirement in 35 U.S.C. 112, first paragraph. See *In re Noll*, 545 F.2d 141, 149, 191 USPQ 721, 727 (CCPA 1976) (unless the means-plus-function language is itself unclear, a claim limitation written in means-plus- function language meets the definiteness requirement in 35 U.S.C. 112, second paragraph, so long as the specification meets the written description requirement in 35 U.S.C. 112, first paragraph)... the invocation of 35 U.S.C. 112, sixth paragraph, does not exempt an applicant from compliance with 35 U.S.C. 112, first and second paragraphs. See *Donaldson*, 16 F.3d at 1195, 29 USPQ2d at 1850; *Knowlton*, 481 F.2d at 1366, 178 USPQ at 493.

Art Unit: 1631

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-4, 7, 8 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The amendments to claim 1 result in certain portions of claim 2 lacking antecedent basis. Claim 1 no longer recites “selected standard gene expression profiles”, or any other profile. Therefore, all the limitations to the correlation information of the profiles lack basis.

Claim 1 does not recite “relevant product information” but merely “product information” so that the “relevant” term in claim 3 lacks basis.

In claim 4, it is unclear how product information of claim 3 further comprises a hyperlink. For example, how does “sequence data from other species” further comprise a hyperlink to facilitate its purchase? Is one purchasing the data, or a piece of DNA?

In claim 7, step (f) it appears there is a typographical error: “production information” should be “product information”

Claim 7 does not recite “relevant product information” but merely “product information” so that the “relevant” term in claim 8 lacks basis.

In claim 9, it is unclear how product information of claim 8 further comprises a hyperlink. For example, how does “sequence data from other species” further comprise a hyperlink to facilitate its purchase? Is one purchasing the data, or a piece of DNA?

Claims 10-12 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: output means or display means for displaying the selected product information and/or product. The claims recite a database, input means, and means for executing data manipulation steps, with no means for communicating the result to the user.

Art Unit: 1631

Claims 10 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As set forth above, claims 10 and 12 recite various “means for” clauses. The specification as filed does not set forth specific structures for performing the means recited. The means for selecting the record, means for identifying correlation information, means for identifying product information etc all lack specific related structures in the specification. See MPEP 2181: 35 U.S.C. 112, sixth paragraph states that a claim limitation expressed in means-plus-function language “shall be construed to cover the corresponding structure...described in the specification and equivalents thereof.” “If one employs means plus function language in a claim, one must set forth in the specification an adequate disclosure showing what is meant by that language. If an applicant fails to set forth an adequate disclosure, the applicant has in effect failed to particularly point out and distinctly claim the invention as required by the second paragraph of section 112.” *In re Donaldson Co.*, 16 F.3d 1189, 1195, 29 USPQ2d 1845, 1850 (Fed. Cir. 1994) (in banc). One of skill in the art would not necessarily be apprised of the specific structures to be used in the claimed systems. For example, it is unclear what software structures or software/hardware combinations are required to perform the steps.

Conclusion

Claims 1-12 appear free of the art of record.

The following is a statement of reasons for the indication of allowable subject matter: The closest prior art of record appears to be WO 00/65421 (Manyak et al). Manyak discloses databases comprising a variety of biological information, including profile information, bioassay information and gene or drug information. Correlation information amongst various subsets of these data are also disclosed. However, Manyak does not disclose selecting a product related to the correlation information, or displaying purchase information related to the selected product.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (571) 272 0723


Art Unit: 1631

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, PhD can be reached on (571) 272 0718. The fax phone number for the organization where this application or proceeding is assigned is 571 273 8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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MARY K. ZEMAN
PRIMARY EXAMINER
AU 1631
5/11/05